

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-5, 8, 11, 12, 15-17, 37-40, 42, 47-49, 55, 56, 59-61, and 74-79 are pending in the application, with 1 and 11 being the independent claims. Claims 15-17, 37-40, 42, 47-49, 55, 56, 59-61, and 74-79 are withdrawn from consideration. Claims 6, 7, 9, 10, 13, 14, 18-36, 41, 43-46, 50-54, 57, 58 and 62-73 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Claims 1, 8, 11 and 42 are amended. Support for amendment to claims 1 and 11 is found in the specification page 20, line 15 through page 21, line 2 and page 17, lines 1-12. Claim 8 was amended merely to remove a number of compounds that lack antecedent basis from the list of claimed compounds and to change the dependence from claim 7 (cancelled) to claim 1. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***The Restriction Requirement***

The Examiner states that the application has been examined to the extent that it reads on a compound of Formula I wherein Ar<sub>3</sub> represents optionally substituted aryl and R<sub>3</sub>-R<sub>10</sub> represent non-heterocyclic groups. The Examiner also stated that all additional

heterocycles pertain to non-elected subject matter. Applicants respectfully traverse this further restriction requirement.

In the present Amendment, Applicants have maintained the claims of Group III (15-17, 37-40, 42, 47-49, 55, 56, 59-61, and 74-79). Under MPEP § 821.04, the method claims of Group III may be rejoined with product claims of Group I when found allowable. Rejoinder is respectfully requested.

***Rejections under 35 U.S.C. § 102***

Claims 1-5, 8, 11 and 12 are rejected under 35 U.S.C § 102 (a), (b), and/or (e) based on public use or sale of the invention and the Applicant's knowledge of references recited in the information disclosure statement of July 27, 2004. Applicants respectfully traverse this rejection.

The Examiner alleges that:

Applicants state in their information disclosure statement filed July 27, 2004 that the claimed hydrazides were available from one or more commercial suppliers or were otherwise known prior to Applicant's priority application.

(Office action page 3, lines 19-21).

The Examiner requested that Applicants submit information regarding references or commercial suppliers of the hydrazide compounds.

Applicants provide the commercial sources of commercially available hydrazide compounds in Exhibit 1. These hydrazides were purchased by Applicant from the sources prior to the filing of the priority application 60/289,803 (May 10, 2001).

Moreover, the genus of compounds in claims 1 does not encompass the commercially available hydrazide compounds. In addition, claims 2 to 5 and claim 8

depend directly or ultimately from claim 1 and can not encompass more than what claim 1 does. Therefore, claims 1-5 and claim 8 are not anticipated by the commercially available compounds.

Moreover, compounds claimed in claim 11 are structurally different from the commercially available hydrazide compounds. Therefore, claims 11 and 12 are also not anticipated by the commercially available hydrazide compounds.

Reconsideration and withdrawal of the rejection of claims 1-5, 8, 11 and 12 under 35 U.S.C § 102 (a), (b) and/or (e) is respectfully requested.

***Rejections under 35 U.S.C. § 103***

Claims 1-5, 8, 11 and 12 are rejected under 35 U.S.C § 103 (a) as unpatentable over Applicants' admissions in the information disclosure statement filed July 27, 2004. The Examiner alleges that the claimed compounds are known and/or are commercially available in the prior art. Applicants respectfully traverse this rejection.

The Examiner asserts that claimed compounds are prima facie obvious because they are embraced by the disclosed formula. The Examiner states that:

[i]t is believed that one having ordinary skill in the art would have found the claimed compounds prima facie obvious, since *they are generically embraced by the disclosed formula* (citations omitted). The requisite motivation for arriving at the claimed compounds stems from the fact that *they fall within the generic class of compounds disclosed by the references or suppliers*. Accordingly, one having ordinary skills in the art would have been motivated to *prepare any of these compounds embraced by the disclosed generic formula*, including those encompassed by the claims

(Office Action page 4, lines 19, through page 5, line 2). Emphasis added.

However, there is no factual basis for the Examiner's statements above because the

hydrazide compounds admitted by Applicants to be in the prior art are not generic. They are the only specifically disclosed compounds. Moreover, in order to establish a *prima facie* case of obviousness over the disclosed hydrazides, there must be some suggestion or motivation to modify the compounds. *In re Grabiak*, 226 U.S.P.Q. 870 (Fed. Cir. 1985). Here, the Examiner has not presented any specific evidence as to why a skilled artisan would be motivated to modify the commercially available hydrazide compounds to give the presently claimed compounds. Accordingly, a *prima facie* case of obviousness has not been established.

The Examiner's reliance on *In re Susi* (440 F.2d 442, 169 USPQ 423 (CCPA 1971)) for the proposition that claimed compounds are obvious if they fall within the disclosed genus is inappropriate because the references disclose discrete compounds and not a genus of compounds. Moreover, Applicants claim a genus (claim 1) and sub-genus (claims 2-5) of hydrazide compounds that do not encompass the disclosed hydrazide compounds. In addition, compounds claimed in claims 8 and 11 are structurally different from those disclosed in the information disclosure statement and Exhibit 1. Therefore, absent a motivation to modify the disclosed compounds and make the claimed hydrazide compounds, the claimed compounds are not obvious over the disclosed compounds.

Reconsideration and withdrawal of the rejection of claims 1-5, 8, 11 and 12 under 35 U.S.C § 103 (a) is respectfully requested.

***Rejections under 35 U.S.C. § 112, first paragraph***

The Examiner has rejected claims 1, 4, 5, 8 and 11 under 35 U.S.C § 112, first paragraph, as failing to comply with the enablement requirements. Applicants respectfully traverse this rejection.

The Examiner alleges that the terms "prodrug" in claims 1, 8 and 11 and "optionally substituted" in claims 1, 4 and 5 are not enabled and claims 1, 4, 5, 8 and 11 allegedly contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention.

To expedite the prosecution of the pending claims, Applicants have amended claims 1 and 11 so that the term "prodrug" is limited to specifically described types of prodrugs. Support for this amendment is found in the specification page 20, line 15 through page 21, line 2. Reconsideration and withdrawal of the rejection of claims 1, 8 and 11 under 35 U.S.C § 112, first paragraph, based on the use of the term "prodrug" is respectfully requested.

Claim 1 is also amended so that the term "optionally substituted" is limited to those substituents specifically disclosed in the application. Support for this amendment is found in page 17, lines 1-12. Applicants, therefore, respectfully request the rejection of claims 1, 4 and 5 under 35 U.S.C § 112, second paragraph, based on the use of the term "optionally substituted" be also withdrawn.

Reconsideration and withdrawal of the rejection of claims 1, 4, 5, 8 and 11 under 35 U.S.C § 112, first paragraph is respectfully requested.

***Rejections under 35 U.S.C. § 112, second paragraph***

The Examiner has rejected claims 1, 4, 5, 8 and 11 under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctively claim the subject matter the applicant regards as the invention. Applicants respectfully traverse this rejection.

Amendment to claims 1 and 11 discussed in the previous section make the terms "prodrug" and "optionally substituted" in claims 1, 4, 5, 8 and 11 definite. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection of claims 1, 4, 5, 8 and 11 under 35 U.S.C § 112, second paragraph.

***Priority Claim***

On page 9, lines 1-6 of the Office Action, the Examiner alleges that Applicants did not comply with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §§ 120 and 119(e). The Examiner alleges that specific reference to the prior application(s) was not provided in the first sentence(s) of the application or in an application data sheet.

Applicants assert that a priority claim in compliance with 37 C. F. R. 1.78(a)(2) requirements was made in the Application Data Sheet filed April 5, 2004. See 37 C.F.R. § 1.76(b)(5) which states that providing the domestic priority information in an Application Data Sheet constitutes the specific reference required by 35 U.S.C. § 119(e) or 120, and need not otherwise be made part of the specification.

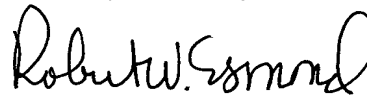
***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

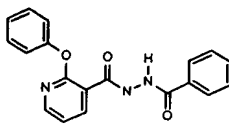


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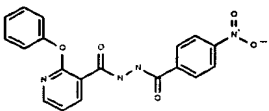
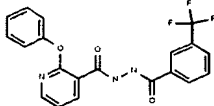
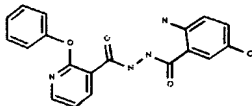
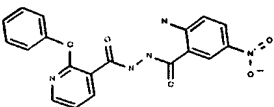
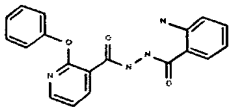
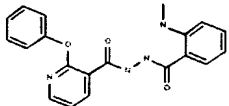
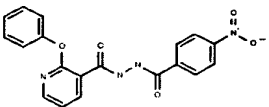
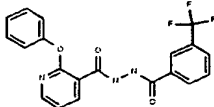
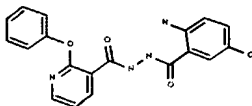
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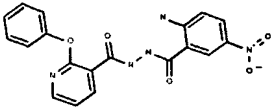
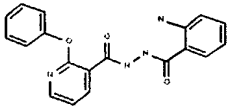
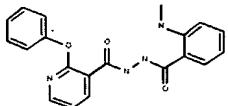
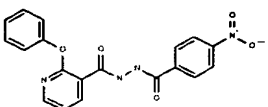
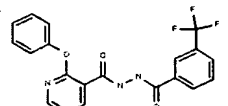
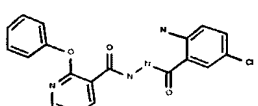
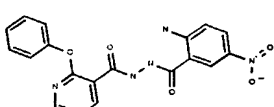
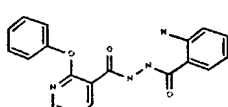
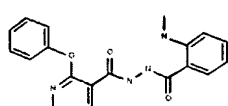
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